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NOTICE OF ALLOWANCE AND FEE(S) DUE

67801 7590 08/13/2010

MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 08/13/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,287	01/04/2007	Anthony Futerman	30227	6293

TITLE OF INVENTION: PARTIALLY DEGLYCOSYLATED GLUCOCEREBROSIDASE POLYPEPTIDE AND CRYSTALS THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	11/15/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

67801 7590 08/13/2010
MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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10/552,287	01/04/2007	Anthony Futerman	30227	6293

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nonprovisional	YES	\$755	\$300	\$0	\$1055	11/15/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
STEADMAN, DAVID J	1656	435-201000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____
Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.**

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67801	7590	08/13/2010	EXAMINER	
STEADMAN, DAVID J				
ART UNIT			PAPER NUMBER	

1656

DATE MAILED: 08/13/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability**Application No.**

10/552,287

Applicant(s)

FUTERMAN ET AL.

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 6/16/10.
2. ☒ The allowed claim(s) is/are 123 and 124.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date See Continuation Sheet
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 4/26/10, 5/23/10, and 7/19/10.

DETAILED ACTION

Status of the Application

- [1] Claims 123-124 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 6/16/10, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicant's amendment to the specification, filed on 6/16/10, is acknowledged.
- [4] Receipt of information disclosure statements, filed on 4/26/10, 5/23/10, and 7/19/10, is acknowledged.
- [5] Receipt of a communication requesting the status of the Petition under 37 CFR 1.48(a), filed on 8/10/09, is acknowledged. The status of this Petition is set forth at [19] at p. 8 of the Office action mailed on 3/16/10.
- [6] Receipt of a communication requesting the status of the amendment to the title of the specification, filed on 9/17/08, is acknowledged. The examiner's response to this amendment is set forth at [15] of the Office action mailed on 4/8/09. As requested in the specification amendment, the title has been amended.
- [7] The claim objections previously applied to claim 123 are withdrawn in view of the instant claim amendment.
- [8] Rejections and/or objections previously applied to claims 129, 133-138, and 157-158 are withdrawn solely in view of the instant amendment to cancel these claims.

Information Disclosure Statement

[9] The information disclosure statements submitted on 4/26/10, 5/23/10, and 7/19/10 were filed after the mailing date of the first Office action on the merits on 3/16/10 (after filing a request for continued examination). The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. A copy of Forms PTO/SB/08 is attached to the instant Office action.

Examiner's Amendment to the Specification

[10] Please enter the substitute sequence listing paper copy filed on 11/19/09 into the application. This amendment is made to perfect the requirements for sequence compliance as noted at paragraph [11] at p. 4 of the Office action mailed on 3/16/10.

Examiner's Amendment to the Claims

[11] An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Jason H. Rosenblum on 8/4/10. Please amend claims 123-124 as follows.

Claim 123. A composition-of-matter comprising a crystal of a glucocerebrosidase polypeptide, wherein the crystal has unit cell dimensions of a = about 107.7 angstroms, b = about

285.2 angstroms and c = about 91.8 angstroms and a crystal space group of $C222_1$, wherein the amino acid sequence of said glucocerebrosidase polypeptide consists of SEQ ID NO: 1, and wherein the amino acid sequence is glycosylated at Asn19 and unglycosylated at Asn59, Asn146 and Asn270 of SEQ ID NO:1.

Claim 124. The composition-of-matter of claim 123, wherein said crystal diffracts X-rays to a resolution of 2.9 angstroms or greater resolution.

Examiner's Reasons for Allowance

[12] The claims are drawn to a composition-of-matter comprising a crystal of the glucocerebrosidase enzyme Cerezyme™ treated with N-glycosidase F, *i.e.*, a glucocerebrosidase polypeptide consisting of SEQ ID NO: 1, which is glycosylated at Asn19 and unglycosylated at Asn59, Asn146 and Asn270 (specification at p. 93, lines 5-7), the crystal having unit cell dimensions of a = about 107.7 angstroms, b = about 285.2 angstroms and c = about 91.8 angstroms and a crystal space group of $C222_1$. It is noted the claims recite the term "about" with respect to the recited numerical values for each of the unit cell dimensions. In accordance with MPEP 2173.05(b).A, the specification provides an indication as to what range is covered by the term "about" at, *e.g.*, p. 81, Table 1.

The closest prior art is the reference of Roeber et al. (*Acta Cryst.* D59:343-344, 2003), which discloses a crystal of untreated Cerezyme™ having crystal space group $C222_1$ and unit cell dimensions of a = 285.0 angstroms, b = 110.2 angstroms and c = 91.7 angstroms. The differences between the claimed crystal and the crystal of Roeber

et al. are: 1) the polypeptide, which is Cerezyme™ treated with N-glycosidase F in the instant claims, which is glycosylated at Asn19 and unglycosylated at Asn59, Asn146 and Asn270 and untreated Cerezyme™ in Roeber, which is glycosylated at Asn19, Asn59, Asn146 and Asn270; and 2) the unit cell dimensions, which are $a = \text{about } 107.7 \text{ angstroms}$, $b = \text{about } 285.2 \text{ angstroms}$ and $c = \text{about } 91.8 \text{ angstroms}$ in the instant claims and $a = 285.0 \text{ angstroms}$, $b = 110.2 \text{ angstroms}$ and $c = 91.7 \text{ angstroms}$ in Roeber.

The prior art undisputedly teaches and/or suggests treating Cerezyme™ with N-glycosidase F (see [21] at pp. 9-12 of the Office action mailed on 3/16/10). However, because of the highly unpredictable nature of protein crystallography (see, *e.g.*, pp. 16-20 of the Office action mailed on 9/17/08), there is no reasonable expectation of success for achieving an isomorphous crystal of Cerezyme™ treated with N-glycosidase F, let alone a crystal having the recited unit cell dimensions. It is noted that the crystallization conditions used to produce the claimed crystal (specification at p. 80, lines 17-20) are distinct from those of Roeber et al. (paragraph bridging pp. 343-344) and there is no evidence of record that applying the crystallization conditions of Roeber et al. to Cerezyme™ treated with N-glycosidase F would have achieved a crystal as encompassed by the claims.

As such, the composition-of-matter of claims 123-124 is allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/
Primary Examiner, Art Unit 1656